

**UNITED STATES INTERNATIONAL TRADE COMMISSION**  
**Washington, D.C.**

<b>In the Matter of</b>	)	
	)	
<b>CERTAIN SILDENAFIL OR ANY</b>	)	<b>Inv. No. 337-TA-489</b>
<b>PHARMACEUTICALLY ACCEPTABLE</b>	)	
<b>SALT THEREOF, SUCH AS SILDENAFIL</b>	)	
<b>CITRATE, AND PRODUCTS</b>	)	
<b>CONTAINING SAME</b>	)	
	)	

**NOTICE OF COMMISSION DECISION TO REVIEW AND REVERSE AN INITIAL  
DETERMINATION TERMINATING THE INVESTIGATION AS TO RESPONDENT  
BIOVEA ON THE BASIS OF A REVISED CONSENT ORDER**

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the U.S. International Trade Commission has determined to review and reverse the presiding administrative law judge's ("ALJ's") initial determination ("ID")(Order No. 21) terminating the investigation as to respondent Biovea on the basis of a consent order. The Commission found that the identification of Biovea and its legal status had not been sufficiently established.

**FOR FURTHER INFORMATION CONTACT:** Wayne Herrington, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-3090. Copies of the Commission's order, the ALJ's ID, and all other nonconfidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone 202-205-2000. General information concerning the Commission may also be obtained by accessing its Internet server (<http://www.usitc.gov>). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <http://edis.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202-205-1810.

**SUPPLEMENTARY INFORMATION:** The Commission instituted this investigation on March 6, 2003, based on a complaint filed by Pfizer, Inc. (“Pfizer”) of New York, New York. 68 *Fed. Reg.* 10749 (March 6, 2003). The complaint, as supplemented, alleged violations of section 337 of the Tariff Act of 1930 in the importation into the United States, sale for importation, and sale within the United States after importation of certain sildenafil or any pharmaceutically acceptable salt thereof, such as sildenafil citrate, and products containing same by reason of infringement of claims 1-5 of Pfizer’s U.S. Patent No. 5,250,534. The Commission’s notice of investigation named Biovea among the respondents.

On June 13, 2003, complainant Pfizer filed a single motion pursuant to Commission rules 210.21(b) and (c) to terminate the investigation as to respondent Ezee Soulnature Healthcare Pvt. Ltd. (“Ezee”) on the basis of a settlement agreement and as to respondent Biovea on the basis of a consent order.

On June 30, 2003, the ALJ issued Order No. 16, terminating the investigation as to respondent Ezee on the basis of a settlement agreement and as to respondent Biovea on the basis of a consent order, subject to deletion of a term in the consent order. On July 24, 2003, the Commission issued a notice extending the deadline for determining whether to review Order No. 16 to permit respondent Ezee, who could only be served with the public version of Order No. 16, an opportunity to file a petition for review. No petitions for review of Order No. 16 were filed.

On August 13, 2003, the Commission issued a notice that it had determined (1) to waive its rule requiring that a motion terminating a respondent on the basis of a consent order include that respondent as a moving party, and (2) to review Order No. 16 in its entirety, specifying certain questions it wished the parties to address on review.

On September 30, 2003, the Commission issued a notice and order that (1) affirmed that part of Order No. 16 terminating the investigation as to Ezee on the basis of a settlement agreement and (2) remanded that part of Order No. 16 terminating the investigation as to Biovea on the basis of a consent order because the identification of Biovea and its legal status was inadequate.

On October 16, 2003, the ALJ issued Order No. 18, ordering Pfizer, Biovea, and the Commission investigative attorney to meet and confer on an appropriate resolution of the Commission’s concerns regarding Biovea expressed in its September 30, 2003, order. On October 30, 2003, those parties submitted a joint response to Order No. 18. On November 3, 2003, the ALJ issued Order No. 20, ordering Pfizer, Biovea, and the Commission investigative attorney to further clarify the legal status of Biovea. On November 7, 2003, those parties filed a second joint submission.

On November 14, 2003, the ALJ issued the subject ID. In that ID, the ALJ found that the submissions clarified the issues raised by the Commission in its September 30, 2003, order. He therefore terminated the investigation “with regard to respondent W/R Group, Inc. d/b/a BioVea as provided herein,” conditioning his ID on a modification of paragraph 3, page 2, of the proposed consent order, which he set out in his ID. No party filed a petition for review of the ID.

Having examined the relevant portions of the record in this investigation, including the ALJ’s ID and the submissions on remand, the Commission determined to review and reverse the ID because the identification of Biovea and its legal status had not been sufficiently established.

The authority for the Commission’s determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. §1337), and in sections 210.21(c) and 210.44-.45 of the Commission’s Rules of Practice and Procedure (19 C.F.R. §§ 210.21(c), 210.44-.45).

By order of the Commission.

Marilyn R. Abbott  
Secretary to the Commission

Issued: December 15, 2003